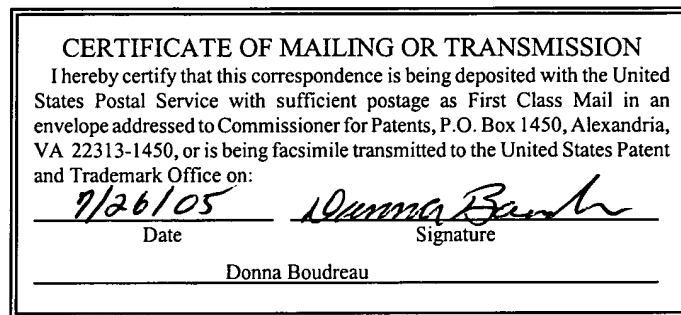


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Giandomenico Russo and Carlo M. Croce
Application No.: 09/441,242 Group Art Unit: 1636
Filed: November 16, 1999 Examiner: Gerald G. Leffers, Jr., Ph.D.
Confirmation No.: 4066

Title: TCL-1 GENE AND PROTEIN AND RELATED METHODS AND COMPOSITIONS



STATEMENT UNDER 37 C.F.R. § 1.806 AND § 1.808

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

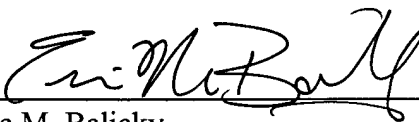
Pursuant to 37 C.F.R. § 1.806 and § 1.808 the undersigned states:

1. The above-referenced application contains reference to two biological deposits. Plasmid, pA11.5, Accession No. 75923; and Plasmid, p20-7SE, Accession No. 75924, were deposited on October 25, 1994 at the American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852, USA, in accordance with the terms of the Budapest Treaty.
2. In accordance with 37 C.F.R. § 1.806, the deposits under Accession Nos. 75923 and 75924 were made for a term of at least thirty years and at least five years after the most

recent request for the furnishing of a sample of the deposit is received by the depository. The deposits under Accession Nos. 75923 and 75924 are stored under agreements that make them available beyond the enforceable life of the patent that issues from the subject application and for which the deposits were made.

3. In accordance with 37 C.F.R. § 1.808(a)(1), access to the deposits under Accession Nos. 75923 and 75924 will be available during the pendency of the above-referenced application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.
4. In accordance with 37 C.F.R. § 1.808(a)(2), and except as permitted by 37 C.F.R. § 1.808(b), all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent on the above-referenced application.
5. The undersigned is an agent of record.

Respectfully submitted,
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

Eric M. Balicky

Registration No.: 57,020

Telephone (978) 341-0036

Facsimile (978) 341-0136

Concord, Massachusetts 01742-9133

Dated: *July 26, 2005*

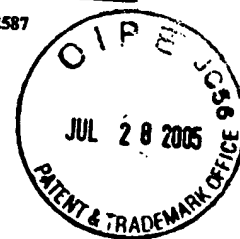


American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 898-055 ATCCNORTH • FAX: 301-770-2587

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM



RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

S. Leslie Misrock, Esq.
Pennie & Edmonds
1155 Avenue of the Americas
New York, NY 10036

Deposited on Behalf of: Raggio Italgene SpA and Thomas Jefferson University (Docket 6754-027)

Identification Reference by Depositor:

ATCC Designation

Plasmid, pAI1.5
Plasmid, p20-7SE

75923
75924

The deposits were accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposits were received October 25, 1994 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested October 31, 1994. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Annette L. Bade, Director, Patent Depository

Date: November 1, 1994

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.27(a))-NONPROFIT ORGANIZATION



DOCKET NUMBER: 3589.1017-001

Applicant or Patentee: Giandomenico Russo and Carlo M. Croce
Application or Patent No.: 09/441,242
Filed or Issued: November 16, 1999
Title: TCL-1 GENE AND PROTEIN AND RELATED METHODS AND COMPOSITIONS

I hereby state that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF NONPROFIT ORGANIZATION Thomas Jefferson University
ADDRESS OF NONPROFIT ORGANIZATION 1015 Walnut Street, Suite 705
Philadelphia, Pennsylvania 19107

TYPE OF NONPROFIT ORGANIZATION:

- ☒ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
☐ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3))
☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
(NAME OF STATE _____)
(CITATION OF STATUTE _____)
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF
LOCATED IN THE UNITED STATES OF AMERICA
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED
STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
(NAME OF STATE _____)
(CITATION OF STATUTE _____)

I hereby state that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.27(a)(3) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in:

- ☐ the specification filed herewith with title as listed above.
☒ the application identified above.
☐ the patent identified above.

I hereby state that the rights under contract or law have been conveyed to and remain with the nonprofit organization regarding the above identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities. No rights to the invention are held by any person who would not qualify as a person under 37 CFR 1.27(a)(1) or by any concern which would not qualify as a small business concern under 37 CFR 1.27(a)(2) or a nonprofit organization under 37 CFR 1.27(a)(3).

Each additional person, concern, or organization having any rights in the invention is listed below:

- ☒ no such person, concern, or organization exists.
☐ each such person, concern, or organization is listed below.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.27(g)(2))

NAME OF PERSON SIGNING Steven E. McKenzie, M.D., Ph.D.

TITLE IN ORGANIZATION OF PERSON SIGNING V.P. of Science Policy and Technology Transfer

ADDRESS OF PERSON SIGNING 1020 Locust Street, Philadelphia, Pennsylvania 19107-6799

SIGNATURE Steven E. McKenzie MD, PhD DATE 4/21/05

July 7, 2005



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Giandomenico Russo and Carlo M. Croce
Application No.: 09/441,242 Group: 1636
Filed: November 16, 1999 Examiner: Gerald G. Leffers Jr., Ph.D.
Confirmation No.: 4066
For: TCL-1 GENE AND PROTEIN AND RELATED METHODS AND COMPOSITIONS

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
<u>7/26/05</u> Date	<u>Donna Boudreau</u> Signature
<u>Donna Boudreau</u> Typed or printed name of person signing certificate	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Amendment for filing in the above-identified application.

- [] Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a Small Entity Statement previously submitted.
- [X] A Small Entity Statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.

The claims fee has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA
TOTAL	7	MINUS *	56	0
INDEP	7	MINUS **	21	0
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				

* not fewer than 20

** not fewer than 3

SMALL ENTITY

	RATE	ADDIT. FEE
X	\$ 25	\$ 0
X	\$ 100	\$ 0
+	\$ 180	\$

TOTAL= \$ 0

OTHER THAN SMALL ENTITY

	RATE	ADDIT. FEE
X	\$ 50	\$
X	\$ 200	\$
+	\$ 360	\$

TOTAL= \$ 0

The Application Size Fee has been calculated as shown below:

(Effective for cases filed on or after December 8, 2004)

Actual Sheets (Including current amendment)	Highest No. of Sheets Paid For (At least 100)	No. of Additional Units Required (Increments of 50 sheets)

SMALL ENTITY

Rate	Total Amount Owed
X \$125	\$[]

OTHER THAN SMALL ENTITY

Rate	Total Amount Owed
X \$250	\$[]

Payment
Sufficient for
up to

[] Sheets

Petition for Extension of Time

[X] Applicant hereby petitions to extend the time to respond to the Office Action dated March 30, 2005 for one month from June 30, 2005 to July 30, 2005. The appropriate fee is set forth below.

[] [For action-specific language in an extension of time, go to insert, file, public folders, firm templates, and select the appropriate paragraph.]

Please charge Deposit Account No. 08-0380 for the following fees:

<input type="checkbox"/>	Petition for [] month Extension of Time	\$ _____
<input type="checkbox"/>	Claims Fee	\$ _____
<input type="checkbox"/>	Application Size Fee	\$ _____
<input type="checkbox"/>	Other Fees:	_____
	_____	\$ _____
	_____	\$ _____
	TOTAL:	\$ <u>0</u>

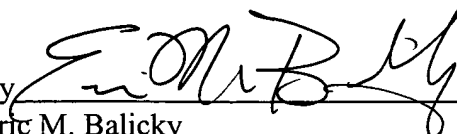
A check is enclosed in payment of the following fees:

<input checked="" type="checkbox"/>	Petition for one month Extension of Time	\$ <u>60</u>
<input type="checkbox"/>	Claims Fee	\$ _____
<input type="checkbox"/>	Application Size Fee	\$ _____
<input checked="" type="checkbox"/>	Other Fees:	_____
	<u>Information Disclosure Statement</u>	\$ <u>180</u>
	_____	\$ _____
	TOTAL:	\$ <u>240</u>

☒ Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to Deposit Account No. 08-0380. A copy of this letter is enclosed for accounting purposes.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 
Eric M. Balicky
Registration No.: 57,020
Telephone (978) 341-0036
Facsimile (978) 341-0136

Concord, Massachusetts 01742-9133

Dated: July 26, 2005